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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,387	01/02/2004	Naoyuki Fukuchi	246515US0DIV	9339

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,387

Applicant(s)

FUKUCHI ET AL.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 21-23 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11, 21-23 and 25-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Preliminary amendment filed 2 January 2004, which amends claims 1-4, 7, 9, 11, and 21-23, cancels claims 12-20 and 24, and add claims 25-34 has been entered. The following Office action is applicable to the pending claims 1-11, 21-23 and 25-34.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a method of producing a protein, are classified in class 530, subclasses 356 and 350.
- II. Claims 21-23, drawn to an isolated polynucleotide encoding the protein, and a process of producing the protein comprising culturing a cell transformed with said polynucleotide, are classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1 and 252.3.
- III. Claims 25-26, drawn to an isolated polynucleotide encoding the protein, and a process of producing the protein comprising culturing a cell transformed with said polynucleotide, wherein the polynucleotide (additionally) is characterized by comprising mutations in the region of the protein (encoded by said polynucleotide): amino acid residues 47-111, or a substitution mutation in residue 81 (Cys → Ala), are classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1, 252.3 and 440.
- IV. Claims 27-30, drawn to an isolated polynucleotide encoding the protein, and a process of producing the protein comprising culturing a cell transformed with said polynucleotide, wherein the polynucleotide is characterized by deletion of amino acid residues (in said protein) which participate in the loop structure between $\beta 2$ and $\beta 3$, or characterized with amino acid substitutions for maintaining the secondary or ternary structures of $\beta 2$ and $\beta 3$, are classified in class 536, subclass 23.1, class 435, subclasses

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69.1, 320.1, 252.3 and 440.

- V. Claims 31-34, drawn to an isolated polynucleotide encoding the protein, and a process of producing the protein comprising culturing a cell transformed with said polynucleotide, wherein the polynucleotide is characterized by mutations in the protein encoded by said polynucleotide, which is substitution of any acidic amino acid residues which C α existing within 10 Å distance from C α of residue 103, are classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1, 252.3 and 440.

The inventions are distinct, each from the other because of the following reasons:

Inventions I is patentably distinct from Inventions II-V because of the materially different structures of the compounds claimed. The Invention I is drawn to polypeptide while Inventions II-V to polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions II, III, IV and V are directed to structurally different polynucleotide molecules because they comprise different structural alteration, e.g., substitution, deletion, which renders the coding sequence of each of said polynucleotides distinct/different despite of function of the encoded protein thereof. The polynucleotides of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571) 272-09525. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.



Samuel W. Liu, Ph.D.

March 9, 2005



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER